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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

19

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/134,014

Applicant(s)

GRUISSEM ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 13-31 is/are pending in the application.
- 4a) Of the above claim(s) 13-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 June 2003 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendments of 13 June 2003 and accompanying arguments have overcome all rejections of record. Upon further consideration, the Examiner agrees that the cited prior art references do not provide the motivation for obtaining the claimed invention with a reasonable expectation of success.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in the rejection.

Claim 1 is indefinite in its recitation of "fusion polynucleotide comprising a sequence encoding a polypeptide...that targets an endogenous gene" as it is unclear whether the polypeptide or the polynucleotide is intended to target the gene. If the latter were intended, the following amendments would obviate this rejection:

In line 4, insert --nucleotide-- before "sequence".

In line 5, delete "that targets an endogenous gene", and insert after "sequence, " the following:

-- wherein the nucleotide sequence encoding the polypeptide sequence of interest targets an endogenous gene, --.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method of identifying homologous recombination comprising plant cell transformation with a heterologous nucleic acid molecule comprising a fusion polynucleotide encoding a reporter sequence linked to another polypeptide sequence of interest, said heterologous nucleic acid molecule further comprising a selectable marker gene, said polypeptide of interest being encoded by a nucleotide sequence which targets an endogenous gene on a plant plastid genome, wherein said method involves the additional step of identifying transformed plant cells by culture on a selective medium prior to the step of detecting the presence of the reporter activity in the plant cells; does not reasonably provide enablement for claims broadly drawn to any targeting sequence or a method which does not involve an initial selection step for transformed plant cells on selective medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for detecting homologous recombination without the use of a selectable marker gene to initially identify transformed cells. The claims are further broadly drawn to a fusion polynucleotide comprising a targeting sequence which encompasses any gene, including those found on the nuclear genome. In contrast, the specification only provides guidance for the use

Art Unit: 1638

of a heterologous nucleic acid molecule comprising a promoterless fusion polynucleotide construct comprising at least one entire exon of the chloroplast *rbcl* gene ligated to a non-selectable reporter gene, said heterologous nucleic acid molecule further comprising a selectable marker gene comprising a promoter, said selectable marker gene outside of the fusion polynucleotide construct. It is noted that the chloroplast genome is substantially smaller than the nuclear genome.

Homologous recombination in transformed plant cells and plants is unpredictable. Risseuw et al teach that transgenes inserted via homologous recombination may be unstable in cultured plant cells (see, e.g., page 717, Abstract). Thykjaer et al teach that the use of non-selectable or even selectable markers as part of the constructs also comprising endogenous genes results in the lack of identification or maintenance of homologous recombination events (see, e.g., page 523, Abstract).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for identifying and obtaining homologous recombination in plant cells transformed with a genetic construct that does not contain a selectable marker gene. Furthermore, undue experimentation would have been required to develop and evaluate methods for obtaining and identifying homologous recombination events with a multitude of endogenous genes in the substantially larger nuclear genome.

Claims 1-7 are deemed free of the prior art, in view of Applicants' arguments in the amendment of 13 June 2003.

Art Unit: 1638

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 7, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.